DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 10, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-54

Laura Willett, Owner/President
Willett Brothers, Inc.
1101 Snake River Avenue
Lewiston, Idaho 83501

WARNING LETTER

Dear Ms. Willett:

A Food and Drug Administration (FDA) inspection was conducted on March 14-15, 2001, at your medical oxygen gas manufacturing and liquid oxygen repacking facility located at 1101 Snake River Avenue, Lewiston, Idaho. Medical gases are drug products as defined by Section 201(g) of the Federal, Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements (Title 21, Code of Federal Regulations (CFR), Part 211) were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in compliance with the GMP regulations.

The deviations included the following:

- Failure to test batches of medical oxygen gas packed in compressed cylinders for identity and purity after the first batch of the day, even though you make more than one batch per day. Your firm does not test one cylinder of product for each uninterrupted filling operation cycle.

- Failure to have a Quality Control Unit (QCU) who has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products.

- Failure to record the percent of calibration for the strength and purity on the maintenance log for the [redacted] between July 2000 to the present.

- Failure to follow your own written procedure of using a scale when filling liquid cryogenic vessels of oxygen USP.

- Failure to follow your own written procedures for the calibration of the temperature thermometer attached to the compressed Oxygen USP cylinders.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, 22201 23rd Drive SE, Bothell, Washington, 98021-4421, to the attention of Lisa M. Elrand, Compliance Officer. Ms. Elrand can be reached at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosure:
FDA 483